Docket No.: 01946/100B861-US2

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Andrea Leone-Bay, et al.

Mail Label No.

Application No.: 10/005,511

Confirmation No.: 2401

Filed: November 7, 2001

Art Unit: 1615

For:

COMPOUNDS AND COMPOSITIONS FOR

Dated:

DELIVERING ACTIVE AGENTS

Examiner: J. M. Spear

## INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

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Application No.: 10/005,511 2 Docket No.: 01946/100B861-US2

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: September 14, 2004

Respectfully submitted,

Jason C Chumney

Registration No. 54,781

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002.OMB 0651-0031

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Sheet 1 of 2.

Substit	ute for form 1449A	/PTO		Complete if Known		
				Application Number	10/005,511	
INF	ORMATI	ON DISC	LOSURE	Filing Date	November 7, 2001	
STATEMENT BY APPLICANT				First Named Inventor	Andrea Leone-Bay	
				Art Unit	1615	
(use as many sheets as necessary)				Examiner Name	James Spear	
Sheet	1	of	2	Attorney Docket Number	01946/100B861 -US2	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Memorandum		
	1	5,935,601	8/10/1999	Leone-Bay, et al.			
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	Te
	31	W095/28920	11/02/1995	Emisphere Technologies, Inc.		✝
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{W:\01				DATE CONSID	DERED:	_

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Sheet 2 of 2.

+	Substitute for form 1449A/I	РТО		Complete if Known		
				Application Number	10/005,511	
	<b>INFORMATION</b>	ON DIS	SCLOSURE	Filing Date	November 7, 2001	
	STATEMEN'	T BY A	PPLICANT	First Named Inventor	Andrea Leone-Bay	
				Art Unit	1615	
	(use as man	y sheets as	necessary)	Examiner Name	James Spear	
She	et 2	of	2	Attomey Docket Number	01946/100B861 -US2	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	r Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the article (						
	65	HO KOC-KAN; et al. "Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication, vol. 27, no. 5: 883-895 (1997)					
	66	LEONE-BAY, A. "Synthesis And Evaluation Of Compounds That Facilitate The Gastrointestinal Absorption Of Heparin"; Journal of Medicinal Chemistry vol 41, 1163-1171 (1998)					
	67	Francia Farmaceutica "γ-(o-Hydroxybenzamido)-Butyric Acid" Chem Abstracts Vol. 10 114838e (1969)	-				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.



lication No. (if known): 10/005,511

Attorney Docket No.: 01946/100B861-US2

## Certificate of Express Mailing Under 37 CFR 1.10

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September 14, 2004 Date

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Information Disclosure Statement (2 pages)

List of References (PTO\SB\08a\b form) (2 pages);

67 References/Publications:

Fee Transmittal for FY 2004 (1 page);

Postcard

Check No. 6091

PTO/SB/17 (10-03) Approved for use through 7/31/2006. OMB 0551-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known TRANSMITTAL 10/005,511 Application Number November 7, 2001 for FY 2004 Filing Date First Named Inventor Andrea Leone-Bay Effective 10/01/2003. Patent fees are subject to annual revision. **Examiner Name** J. M. Spear RADEM! Applicant claims small entity status. See 37 CFR 1.27 1615 Art Unit TOTAL AMOUNT OF PAYMENT (\$) 180.00 Attorney Docket No. 01946/100B861-US2 METHOD OF PAYMENT (check all that apply) FEE CALCULATION (continued) 3. ADDITIONAL FEES x Check Other None Card Order Deposit Account: Small Entity Large Entity Deposit 04-0100 Fee Account Fee Description (\$) Code (\$) Code Fee Paid Deposit 1051 130 2051 65 Surcharge - late filing fee or oath Darby & Darby P.C. Name Surcharge - late provisional filing fee or cover 1052 50 2052 25 The Director is authorized to: (check all that apply) X Credit any overpayments Charge fee(s) indicated below 1053 130 1053 130 Non-English specification X Charge any additional fee(s) or any underpayment of fee(s) 1812 2.520 1812 2,520 For filing a request for ex parte reexamination Requesting publication of SIR prior to 1804 920\* 1804 920\* Charge fee(s) indicated below, except for the filing fee Examiner action Requesting publication of SIR after to the above-identified deposit account 1805 1,840 1805 1.840 Examiner action **FEE CALCULATION** 110 2251 Extension for reply within first month 1. BASIC FILING FEE 2252 1252 420 Extension for reply within second month Large Entity Small Entity 1253 2253 950 Extension for reply within third month Fee Fee Paid Fee Description 1254 1,480 2254 740 Extension for reply within fourth month Code (\$) Code (2) 1001 770 2001 385 Utility filing fee 2.010 2255 1,005 Extension for reply within fifth month 1002 340 2002 170 Design filing fee 1401 330 2401 165 Notice of Appeal 1003 530 2003 265 Plant filing fee 1402 330 2402 165 Filing a brief in support of an appeal 2004 385 1004 770 Reissue filing fee 1403 290 2403 145 Request for oral hearing 2005 1005 160 80 Provisional filing fee 1451 1,510 1451 1,510 Petition to institute a public use proceeding 1452 110 2452 55 Petition to revive – unavoidable SUBTOTAL (1) (\$) 0.00 1453 2453 1.330 665 Petition to revive - unintentional 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE 1501 1,330 2501 665 Utility issue fee (or reissue) Extra 1502 480 2502 240 Design issue fee Fee Paid below Claims Total Claims 0.00 2503 1503 640 320 Plant issue fee Independent 1460 130 1460 130 Petitions to the Commissioner 0.00 Claims 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) Multiple Dependent 1806 180 1806 Submission of Information Disclosure Stmt Large Entity Small Entity Fee Fee Recording each patent assignment per Fee Description 8021 40 8021 (\$) Code (\$) property (times number of properties) 1202 18 2202 Claims in excess of 20 Filing a submission after final rejection 9 1809 770 2809 385 (37 ČFR 1.129(a)) 2201 1201 86 43 Independent claims in excess of 3 For each additional invention to be 1810 770 2810 385 1203 290 2203 145 Multiple dependent claim, if not paid examined (37CFR 1.129(b)) 1204 86 2204 \*\* Reissue independent claims 770 1801 2801 385 Request for Continued Examination (RCE) over original patent Request for expedited examination 900 1802 1205 18 2205 \*\* Reissue claims in excess of 20 of a design application and over original patent Other fee (specify) Information Disclosure Statement 180.00 SUBTOTAL (2) (\$) 0.00 \*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 180.00 \*\*or number previously paid, if greater; For Reissues, see above SUBMITTED BY (Complete (if applicable)) Registration No. Name (Print/Type) Jasd C. Chulhney 54,781 (212) 527-7765 Telephone (Attorney/Agent) Signature Date September 14, 2004

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